



Moeller Medical GmbH & Co. Kg
Bill Kelley
Contact Person
23832 Via Monte
Coto De Caza, California 92679-4001

June 8, 2021

Re: K072793

Trade/Device Name: Liposat Basic (infiltration Pump), Model 92-007 688
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QPB

Dear Bill Kelley:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated March 4, 2008. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Cindy Chowdhury, OHT4: Office of Surgical and Infection Control Devices, 240-402-6647, Cindy.Chowdhury@fda.hhs.gov.

Sincerely,

Cindy Chowdhury -S

Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 4 2008

Moeller Medical GmbH & Co. KG
% Moeller Medical
Mr. Bill Kelley
23832 Via Monte
Coto De Caza, California 92679-4001

Re: K072793

Trade/Device Name: Suction Lipoplasty System (containing the Liposat Basic
infiltration pump)

Regulation Number: 21 CFR 878.5040

Regulation Name: Suction lipoplasty system

Regulatory Class: II

Product Code: MUU

Dated: February 6, 2008

Received: February 11, 2008

Dear Mr. Kelley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5. Indications for Use Statement

Indications for Use

510(k) Number (if known):

K072793

Device Name:

Suction Lipoplasty System (containing the Liposat Basic infiltration pump)

Indications for Use:

For aesthetic body contouring.

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number

K072793

Page 1 of 1

510(k) Summary

"This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92."

"The assigned 510(k) number is K072793"

1. Submitter Information:

Möller Medical GmbH & Co. KG
Wasserkuppenstrasse 29-31
D36043 Fulda
Germany

Contact person:

Bill Kelley
23832 Via Monte
Coto de Caza, CA 92679-4001
Phone: (949) 292-8477
Fax: (509) 479-4840

2. Name of Device:

Common Name: Suction Lipoplasty System

Proprietary Name: Liposat® Basic (infiltration pump), model # 92 007 688; is a component of the Moller Medical Lipoplasty System.

3. Classification: Suction Lipoplasty System, Class II
21 CFR § 878.5040 (1998)

4. Product Code: MUU

5. Substantial Equivalence:

The original Liposat infiltration pump (model # 00 002 274), one of the components which make up the Möller Medical Suction Lipoplasty System, has been modified to make it easier to use. The modified version of the Liposat infiltration pump is called the Liposat Basic infiltration pump (model # 92 007 688), and is substantially equivalent to the original Liposat infusion pump in terms of intended use, design, operating principles, and materials.

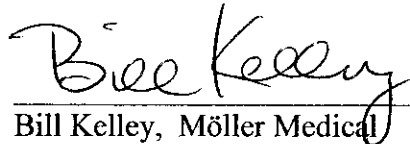
Moller Medical 510(k): K053451 - Containing the original Liposat infiltration pump

6. Device Description:

The Liposat Basic infiltration pump is one of the components that make up the Möller Medical Lipoplasty System. Like the original Liposat infiltration pump, the Liposat Basic is an electrically powered infiltration/peristaltic pump.

7. Intended Use: Aesthetic Body Contouring

8. Signature of Applicant:


Bill Kelley, Möller Medical